

**JUL - 9 2001**

**Submitter:**

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**Date Prepared:**

November 23, 2000

**1. Definition and Intended Use**

The CG-930P is a Doppler ultrasound oscillations transducer intended for monitoring fetal Heart Rate (FHR).

The CG-940P is a Strain gauge transducer intended for monitoring the relative pressure of the Maternal Uterine Activity (TOCO).

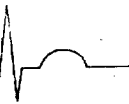
The CG-930P US Transducer and the CG-940P TOCO transducer are classified as Class II medical devices.

**2. Performance and Safety Standards**

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Act for FHR and TOCO transducers.

The CG-930P US Transducer and the CG-940P TOCO Transducer are designed to meet the requirements of the following regulatory and normative documents:

- (1) AIUM: "Acoustic Output Measurements Standard for Diagnostic Ultrasound Equipment", May 1998.
- (2) AIUM: "Medical Ultrasound Safety", 1994.
- (3) AIUM: "Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment", January 1998.
- (4) IEC 1266 "Ultrasonics - hand-held Doppler Fetal Heartbeat Detectors- Performance requirements and methods of measurements and reporting", December 1994.
- (5) IEC 601-1: "Medical electrical equipment Part 1: General requirements for safety", 1995.
- (6) IEC 601-2: "Medical electrical equipment Part 2: Particular Requirements for the safety of ultrasound medical diagnostic and monitoring equipment", Draft October 1999.
- (7) FDA Guide: "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound System and Transducers", September 1997.



### 3. Substantial Equivalence

The CG-930P US transducer is substantially equivalent to its predicate HP M1356A (K921957) Ultrasound Transducer since both devices have:

- The same intended use, and
- The same principles of operation, features and technological characteristics.

The CG-940P TOCO transducer is substantially equivalent to its predicate HP M1355A (K921957) External TOCO transducer since both devices have:

- The same intended use, and
- The same principles of operation, features and technological characteristics.

### 4. Material differences

The Ultrasound Central Frequency in the CG-930P US Transducer is 2.25 MHz while in HP M1356A (K921957) it is 1.024 MHz

The CG-940P TOCO Transducer is smaller and lighter than HP M1355A (K921957) External TOCO transducer.

### 5. Design Controls and Hazard Analysis

The Card Guard's product design procedure, and QA and QC policy, formalize the design and production process and assure that all respective requirements are met. In the framework of the Design Controls the laboratory testing was conducted to verify and validate the compliance of CG-930P and CG-940P with all the design specifications.

The testing included:

- Verification Tests
- Validation tests
- Environmental Tests

The devices biocompatibility was evaluated and found to be satisfactory.

The devices Level of Concern criteria were evaluated and they were characterized as systems with moderate level of concern.

The System Safety and Risk analysis conducted for CG-930P and CG-940P provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly effect the patient.

### 6. Conclusions

The CG-930P US Transducer and the CG-940P TOCO Transducer are safe and reliable devices. Their material composition and of operation present no adverse health effect or safety risks to patients when used as intended.

The conclusions drawn from clinical and laboratory testing of CG-930P and CG-940P demonstrate that the devices are as safe, as effective and perform as well as or better than the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Leonid Trachtenberg  
Chief Engineer  
CARD GUARD Scientific Survival, Ltd.  
2 Pekeris Street, POB 527  
Rehovot, 76100  
ISRAEL

Re: K003876  
CG-930P Ultrasound Transducer and  
CG-940P TOCO Transducer  
Dated: April 4, 2001  
Received: April 11, 2001  
Regulatory Class: II  
21 CFR §884.2660/Procode: 85 HEL  
21 CFR §884.2720/Procode: 85 HFM

Dear Mr. Trachtenberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number: K003876

1. The CG-930P US Transducer is an ultrasound device intended for use as an accessory for Card Guard CG-900 Maternal/Fetal Monitor (K960553) for the purpose of antepartum fetal heart rate detection and measurement.
2. The CG-940P TOCO Transducer is a tocodynamometric device intended for use as an accessory for Card Guard CG-900 Maternal/Fetal Monitor (K960553) for the purpose of antepartum uterine contractions detection and measurement.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K003876